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DEVICE TO MONITOR THE PENETRATION OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

[0001] The present invention concerns the domain of spinal surgery, and more particularly the monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

[0002] The prior art is already familiar with devices used to follow the penetration of an instrument in an anatomic structure, in particular a bone structure.

[0003] We are aware of European patent EP0607688 describing a procedure and a system for the insertion of a pedicular vertebral screw, consisting of applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

[0004] We are also aware of a solution consisting of measuring the modification in the impedance of the region neighbouring the explored bone cavity, using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to detect the gaps in bone matter, for example during an operation preparing for the insertion of a pedicular screw in a vertebra.

[0005] The information gathered with such a solution is difficult to interpret, since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

[0006] In addition, the device proposed is not very practical since it first requires a calibration (reference related to soft tissue).

[0007] Finally, such a device remains not very easy to manipulate due to the presence of external cables.

[0008] The purpose of the invention is to correct these disadvantages by proposing an improved device, whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

[0009] The present invention also aims at proposing an autonomous device, not requiring external cabling.

[0010] The present invention also aims at proposing a device offering improved and safer drilling conditions by informing the operator of the formation of gaps.

[0011] For this purpose, according to its most general acceptation, the invention concerns a device to monitor the penetration of an instrument in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes located on the aforementioned instrument and a means to measure the impedance between the aforementioned electrodes, and it is remarkable in that the aforementioned electrodes are located on the aforementioned penetration instrument so as to present a coinciding and constant contact surface as a function of the degree of entry of the aforementioned penetration instrument in the aforementioned bone structure.

[0012] More precisely, the invariability of the contact surface of the electrodes during the entry of the aforementioned penetration instrument is obtained by the dimensions of the aforementioned surface with respect to the dimensions of the hole formed in the bone structure by the aforementioned penetration instrument, since the dimensions of the aforementioned contact surface should not exceed those of the hole formed by the aforementioned penetration instrument.

[0013] The term “contact surface” refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the aforementioned penetration instrument.

[0014] Preferably, the aforementioned device comprises an electrode coinciding with the distal surface of the aforementioned penetration instrument.

[0015] Distal surface refers to the surface of the distal end of the aforementioned penetration instrument.

[0016] According to a first variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are coaxially placed and separated by an insulation.

[0017] According to one variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are symmetrically placed with respect to a longitudinal axis of the aforementioned penetration instrument.

[0018] According to another variant of the invention, the aforementioned device comprises a plurality of electrodes coinciding with the distal surface of the aforementioned penetration instrument.

[0019] According to an advantageous mode of implementation of the invention, the aforementioned device comprises at least one electrode presenting a contact surface laterally coinciding with the aforementioned penetration instrument.

[0020] Advantageously, the aforementioned electrode at least presents an annular contact surface.

[0021] Advantageously, the aforementioned device comprises at least two electrodes presenting an annular lateral contact surface.

[0022] Advantageously, the aforementioned device comprises a main electrode coinciding with the distal surface of the aforementioned penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

[0023] According to a preferred mode of implementation of the invention, the aforementioned device also comprises means of signalling producing a signal at the time of detection of a variation in the impedance by the aforementioned means of measurement.

[0024] Advantageously, the signal produced is a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

[0025] Therefore, when the aforementioned instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the aforementioned instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

[0026] Advantageously, the aforementioned device comprises a central channel for the passage of an additional instrument.

[0027] The invention will be better understood upon reading the following description, referring to the appended figures where:

- figures 1A and 1B respectively illustrate a front section view and a longitudinal section view of a drilling instrument forming the exploration device of the invention;
- figure 2 illustrates a front section view of a first variant of the drilling instrument;
- figure 3 illustrates a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

- figure 4 illustrates a longitudinal section view of a second variant of the drilling instrument;

- figure 5 illustrates a perspective view of a third variant of the drilling instrument;

- figure 6 illustrates a longitudinal section view of a penetration instrument comprising a tap; and

- figure 7 illustrates a longitudinal section view of the penetration instrument according to another variation of the drilling instrument.

[0028] The device according to the invention is a device to monitor the penetration of an instrument in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electric impedance.

[0029] The aforementioned electrodes, located on the aforementioned penetration instrument (1), are configured to present a contact surface that remains constant during the penetration of the aforementioned penetration instrument.

[0030] The aforementioned electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

[0031] Therefore, since the impedance of the pedicular tissue is strictly superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

[0032] The aforementioned device also comprises means of signalling producing a specific signal at the time of the detection, by impedometer, of a variation in impedance, and therefore the penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, -).

[0033] A preferred example of the operating principle of the signalling of the detection of a gap is described below (figure 3).

[0034] In the following section, the penetration instrument consists of a drilling instrument (1). However, the configurations presented below are of course applicable to other penetration instruments (tapping, curettage, spatulage, -).

[0035] Figures 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the aforementioned exploration device according to the invention.

[0036] In this first configuration, the drilling instrument (1) has, at the distal end, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

[0037] Electrode (2) comprises, in this example of implementation, the positive pole of the aforementioned electronic device, electrode (3) the negative pole. It is of course obvious that this is only an example of implementation, and that the man skilled in the art may create an electronic device whose positive pole will consist of electrode (3) and negative pole of electrode (2) without going beyond the invention.

[0038] Each electrode (2, 3) is arranged so as to coincide with the distal surface of the aforementioned drilling instrument (1).

[0039] In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the aforementioned drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

[0040] During the penetration of the instrument (1) in the bone structure, a signal is given off by the aforementioned means of signalling when a variation in the impedance measured between

the aforementioned electrodes (2, 3) is detected by the impedometer, indicating the formation of a gap.

[0041] At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if he so desires, then modifies the path of the drilling instrument (1) so as to return to the bone cortex.

[0042] Figure 2 illustrates a second configuration of the drilling instrument (1) comprising the aforementioned exploration device.

[0043] In this second configuration, the penetration instrument (1) presents two electrodes (2, 3) of sensibly identical circular section its the distal end. The aforementioned electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

[0044] Since the position of the aforementioned electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

[0045] Since the number and shape of the electrodes is here provided by way of example, it is understood that the aforementioned penetration instrument (1) may present a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the aforementioned instrument (1).

[0046] Figure 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the aforementioned means of signalling as a function of the impedance measured between the electrodes.

[0047] According to one preferential mode of implementation of the invention, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear (see figure 3). Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The aforementioned means of signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

[0048] However, when the end of the instrument enters surrounding soft tissue, the practitioner is informed of this by an increase in the frequency and an acceleration in the rhythm of the signal.

[0049] Therefore, following this configuration, a small variation of the impedance in the bone is not heard while any variation in the impedance related to the penetration of the instrument in the surrounding soft tissue, as small as it may be, will be strongly heard.

[0050] In the same way, it is possible to create penetration instruments presenting other functionalities.

[0051] In particular, the aforementioned drilling instrument (1) may advantageously comprise at lease one electrode (7) coinciding with the lateral surface of the aforementioned drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling instrument (1) (figure 7). It will thereby be possible, due to the configuration of the aforementioned drilling instrument (1) to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone

cortex by means of electrodes (5, 6). For this purpose, the positioning of a lateral electrode consisting of a rod going to the distal end should be avoided. In fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0052] Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument in order to form annular bands of contact coinciding with the surface of the drilling instrument (1) (figure 4).

[0053] According to one variant of the invention, the electrodes will be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes will enable the volumetric detection of the perforations (figure 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

[0054] Figure 6 also illustrates the implementation of a penetration instrument configured for tapping. Advantageously, the aforementioned instrument (1) comprises a distal end in the form of a point and the lateral wall presents cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the aforementioned instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1) but also laterally with respect to the wall of the aforementioned instrument (1) and provoked by at least one of the cutting stops.

[0055] The invention is described above by way of example. It is understood that the man skilled in the art is able to create different variants of the invention without going beyond the framework of the patent.